Statement to the
Subcommittee on Criminal Justice,
Drug Policy and Human Resources,
Committee on Government Reform,
U.S. House of Representatives

Hearing on Clinical Lab Quality: Oversight Weaknesses Undermine Federal Standards

Statement Presented by
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President,
College of American Pathologists

June 27, 2006

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The College of American Pathologists (CAP) is pleased to appear before the Subcommittee on Criminal Justice, Drug Policy and Human Resources for its hearing of issues related to the Government Accountability Office (GAO) report on Clinical Lab Quality. The CAP thanks the subcommittee's chairman, Rep. Mark Souder, R-Ind., and Rep. Elijah Cummings, D-Md., the ranking member, for recognizing the need to ensure the highest quality laboratory testing.

I am Thomas M. Sodeman, MD, FCAP, president of the CAP, a medical specialty society of nearly 16,000 board-certified physicians who practice clinical or anatomic pathology, or both, in community hospitals, independent clinical laboratories, academic medical centers and federal and state health facilities. The CAP inspects and accredits more than 6,000 laboratories worldwide. The CAP has deemed status from the Centers for Medicare and Medicaid Services (CMS), meaning its inspection process meets or exceeds the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

We are here today to provide our perspective on the GAO report on Clinical Lab Quality and to update the committee on the CAP's recent initiatives to improve its Laboratory Accreditation Program (LAP). We were pleased to work with the GAO on this report and appreciate the opportunity to provide comments and testify before this subcommittee. As an organization dedicated to improving laboratory medicine and patient care, we take seriously the findings and recommendations of the GAO. The CAP will analyze the report to assess if there are any additional steps that the CAP needs to take to address issues identified as areas of concern regarding our accreditation program.

Ultimately, the most important outcome for patients is consistently accurate laboratory results. As noted by GAO, the only comparative data available at this time to evaluate the quality of laboratory results in a systematic way is proficiency testing data.

Beginning in 2004, following the events at Maryland General Hospital, the CAP initiated its own evaluation of its LAP. The testimony we presented to this subcommittee on May 18 and July 7 of 2004 included information on those changes we had implemented by those dates. Since those hearings, the CAP announced that it has implemented and planned additional initiatives that are designed to

- Strengthen our inspection process
- Ensure consistency through enhanced, required training for inspectors
- Improve monitoring to ensure sustained compliance
- Reaffirm public confidence in objectivity of the accreditation process

In its report, the GAO acknowledges many of our new initiatives, including the following:

Moving to unannounced inspections
The CAP's move to unannounced inspections directly addresses the GAO's concern related to the accreditation system's ability to emphasize continuous regulatory compliance and adds credibility to the accreditation survey's conclusions as to the laboratory's ability to provide quality patient care. We began phasing in unannounced inspections this spring. By July 3, nearly 100 percent of all CAP inspections will be unannounced, with the exception of some federal facilities that cannot accept unannounced inspections due to security measures.

Enhanced and required training for all CAP inspectors
The CAP'S new mandatory inspector training addresses the GAO's concerns about using active and current laboratory professionals to conduct CAP surveys. This training will supplement their years of professional experience with specific guidance on inspection techniques. The CAP will require both team leaders and team members to successfully complete training within two years prior to inspections. This combination of professional experience in the laboratory and training in advanced inspection techniques makes CAP inspectors uniquely qualified to ensure compliance with CLIA standards.

Mandatory signage to facilitate reporting of quality complaints
The CAP's "anonymous complaint" poster, which was noted in the GAO report, was required by October 2004 to be displayed in all CAP-accredited laboratories. The CAP poster promotes the CAP toll-free reporting phone line that provides prompt and confidential routing of complaints and quality concerns. The CAP poster policy also includes "whistleblower" protections that shield the reporting laboratory worker from employer retaliation.

Strengthened conflict of interest policies
It is important to note that the CAP has always had policies and procedures to protect against conflicts of interest interfering with the objectivity of the inspection process. As a result of the GAO findings we have recently strengthened those policies by making the policies more comprehensive and explicit. Conflicts of interest is something that requires continued vigilance, so the CAP will continue to closely monitor this issue to determine if further actions are necessary.

Development of integrated data system to assess laboratory quality
The CAP is investing $9 million dollars over the next two years in new information systems and processes to strengthen our ability to monitor a laboratory for sustained compliance throughout its two-year accreditation cycle. The system will integrate quality factors, such as proficiency testing results and trend analysis, inspection findings and complaints, that contribute to a knowledge management system which will be utilized to support more effective accreditation decision-making that relies upon a comprehensive, multidimensional assessment of laboratory performance.

The GAO report provides valuable insights and new information for the CAP to consider as it strives to continuously improve its program. There are also portions of the report where we have a different perspective.

The CAP believes that the GAO underestimates the value of utilizing laboratory professionals in the inspection process. Our teams are multidisciplinary teams of laboratory professionals who have current expertise working in the laboratory, and who are quite familiar with the CLIA requirements. The

available evidence suggests that the CAP system is comparable to other models. For example, the CAP believes that the proficiency testing data cited in the report, for the most part, demonstrates that laboratories accredited by the CAP perform better on proficiency testing than those that are not. We believe that is a relevant measure of the quality of testing performed by laboratories accredited by the CAP.

We also have to keep in mind that CAP-accredited laboratories voluntarily choose CAP accreditation, which includes requirements that are more stringent than CLIA. We believe that this dedication to enhanced quality by laboratory professionals demonstrates a commitment to undertake more than is required by the federal government to assure quality laboratory testing.

With respect to the educational function of CLIA, as the GAO correctly noted, CLIA neither requires nor precludes an educational role for surveyors. The CAP believes that these dual objectives are not mutually exclusive and that education is an inherent and important outcome to the inspection process of identifying and correcting deficiencies. The CAP believes that the dual objectives should be complimentary, however, we recognize that the primary purpose of the CLIA statute is to ensure minimum standards.

The GAO also was charged with examining the quality of laboratory testing and was unable to make a determination about this issue. The CAP believes there are inherent challenges to measuring the quality of laboratory testing due to the complexity of the issue, which is why we are working to develop better systems for detecting laboratories with quality issues that potentially impact patient care.

Much of the report is devoted to examining federal oversight of CLIA. In general, we believe that CLIA provides for adequate federal oversight for ensuring accurate laboratory testing and promoting ongoing quality improvement. Over the years, the CAP has worked constructively with CMS and other accrediting entities. However, we're particularly pleased with the CMS Partners Initiative, which provides a forum for the sharing of information among all accrediting entities and provides a forum for the discussion of best practices in laboratory inspection and accreditation. We believe this enhanced CMS initiative is a strong indication of the commitment of the agency and all of the accrediting and oversight entities to improve our communication and strengthen the collaboration necessary to ensure laboratory quality.

Conclusion

The CAP accreditation program is dedicated to a single mission: raising the quality of laboratory testing to improve patient care. As with the laboratories we accredit, we are committed to the continuous improvement of our program and therefore take seriously the analysis provided in this report. We believe our actions demonstrate this commitment.

The CAP thanks the subcommittee for its interest in ensuring the highest quality laboratory testing and is firmly committed to working with Congress, CMS and other oversight entities and accrediting organizations on ways to ensure laboratory quality.